

MULTI-ACTION ANTISEPTIC- cetylpyridinium chloride rinse
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Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Solimo 299.005 299AK-AL

claims

For better oral hygiene
and fresher breath

active ingredients

Cetylpyridinium Chloride 0.07%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

for this product

Stop use and ask a dentist if

- gingivitis, bleeding or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age.

if more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control center right away.

Directions

- adults and children 6 years & older: rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day
- do not swallow
- children 6 years to under 12 years of age: supervise use
- when used after brushing, rinse mouth with water first

- children under 6 years of age: do not use

Other information

- this rinse is not intended to replace brushing or flossing

inactive ingredients

water, glycerin, flavor, poloxamer 188, sodium saccharin, propylene glycol, sodium benzoate, sucralose, benzoic acid, blue 1

disclaimer

This rinse may cause temporary staining to the surface of teeth. This is not harmful and adequate brushing may prevent its occurrence.

Adverse reactions

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Principal Display Panel

Solimo

Multi Action

Antiseptic Rinse

ANTIGINGIVITIS/ANTIPLAQUE

MOUTH RINSE

Fresh mint

Alcohol free

1L (33.8 FL OZ)





SOLIMO

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MOUTH RINSE

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L0017604FA

MULTI-ACTION ANTISEPTIC

cetylpyridinium chloride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-299	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7JIOJV3)		CETYLPIRIDINIUM CHLORIDE	0.7 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLOXAMER 188 (UNII: LQA7B6G8JG)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
BENZOIC ACID (UNII: 8SKN0B0MIM)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/25/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part356		04/25/2018	

Labeler - Amazon.com Services LLC (128990418)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72288-299)